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Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852 Docket # 97N484S

Dear Sir:

I am writing to comment about the proposed FDA regulation that appeared in the Federal Register of September 30, 1999. I oppose the proposal that the FDA regulate some types of allograft bone as medical devices. I am in agreement with the FDA regulating the safety of the tissue that bone banks currently provide. However, I do not agree with regulating allograft as a medical device. If passed, the proposal would curtail the supply of bone products on which I currently rely for treating patients.

I therefore strongly oppose the proposed FDA regulation.

Thank you for your consideration of my concern.

Sincerely,

Frank P. Cammisa, Jr., M.D.

Chief, Spine Service

The Hospital for Special Surgery

FPC/dp

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